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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,890	12/21/2001	William M. Canfield	203510US77	5459

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/023,890

Applicant(s)
Canfield

Examiner
Rebecca Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 23, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above, claim(s) 18, 36-55, and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-35, and 56-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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Applicant's election with traverse of Group I, Claims 1-17, 19-35, and 56-64 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that there would not be any undue burden of search for the coexamination of all groups. This is not found persuasive because as previously shown all of the groups are separately classified and thus have different areas of search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 18, 36-55 and 65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 19-35, and 56-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/023,889. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-17, 19-35 and 56-64 are generic to all that is recited in claims 1-17 of copending application 10/023,889. That is, claims 1-17 of copending application 10/023,889 fall entirely within the scope of claims 1-17, 19-35 and 56-64 or, in other words, claims 1-17, 19-35 and 56-64 are anticipated by claims 1-17 of copending application 10/023,889. Specifically, the methods of claims 1-17 of copending application 10/023,889 are

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identical to the methods of claims 1-17, 19-35 and 56-64 of the instant application except for the addition of a further step (i.e., culturing the lectin resistant cells in the presence of deoxymannojirimycin and kifunensine). As the methods of Claims 1-17, 19-35 and 56-64 of the instant application all recite the transitional phrase "comprising", the methods of the copending application anticipate the instant claims

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11, 12, 16, 29, 30, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 12, 16, 29, 30, and 34 are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". In the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear how homologous to the sequence of a gene encoding SEQ ID NOS:1, 3, 6, or 17, a sequence must be to be included within the scope of these claims.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Mulligan et al. (US Patent 6,224,858).

Mulligan et al. teach a method of producing viruses comprising envelope glycoproteins lacking sialic acid such that they are rendered a ligand for the asialoglycoprotein receptor on hepatocytes. The method comprises transducing a mammalian cell with viral nucleic acid which encodes the envelope glycoproteins, culturing the cells in the presence of a lectin to isolate mutants of the producer cells incapable of adding terminal sialic acids to the envelope glycoprotein and then producing and isolating the virus from these mutant cells. (See particularly column 10, lines 34-54). This anticipates Claims 1 and 56. Claim 19 was not included as the envelope glycoproteins produced by the method of Mulligan et al. still have terminal galactose residues and thus are not deficient in complex carbohydrates

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(defined on page 10 of the specification as completely lacking detectable complex carbohydrates).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 19-24, and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Hove et al. in view of Mulligan et al. (US Patent 6,224,858) and Gottlieb et al.

Van Hove et al. teach the recombinant production of lysosomal acid α -glucosidase in CHO cells and the use of this enzyme for enzyme replacement therapy of Pompe's disease. Van Hove teach that acid α -glucosidase is targeted to lysosomes via the mannose-6-phosphate receptor (page 65). It is well known in the art that the mannose 6-phosphate receptor binds to a high-mannose core oligosaccharide which has been phosphorylated.

Mulligan et al. is discussed above.

Gottlieb et al. teach that treatment of CHO cells with the lectin ricin and selection of ricin resistant mutants produces cells with 53% more mannose than present in the parent cells.

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Therefore, it would have been obvious to one of skill in the art to treat the CHO cells of Van Hove et al. with ricin and select resistant mutants as one would expect the acid α -glucosidase produced from said resistant cells to have significantly more mannose 6-phosphate (M6P) residues than the cells of Van Hove et al. One would have been motivated to do so in view of the known importance of M6P residues for lysosomal targeting. One would have had a reasonable expectation of success in view of the teaching of a similar lectin resistance selection method by Mulligan for increasing the number of sites for binding a glycoprotein to a receptor specific for a specific oligosaccharide structure.

Claims 7, 11-14, 16, 17, 25, 29, 30-32, 34, 35, and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Hove et al. in view of Mulligan et al. (US Patent 6,224,858) and Gottlieb et al. as applied to claims 2-6, 19-24, and 57-61 above, and further in view of Bao et al. and Kornfeld et al.

Van Hove et al., Mulligan et al., and Gottlieb et al. are discussed above.

Bao et al. and Kornfeld et al. teach the isolation of the enzymes responsible for the phosphorylation of the core mannose oligosaccharide structure of lysosomal hydrolases and the use of these enzymes for the generation of mannose 6-phosphate groups on

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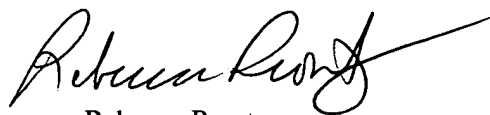
purified lysosomal hydrolases for enzyme replacement therapy (see page 23209 of Kornfeld et al.)

Therefore, it would have been obvious to one of skill in the art to further treat the high-mannose containing acid α -glucosidase produced from ricin resistant cells as made obvious by the combined disclosures of Van Hove et al., Mulligan et al., and Gottlieb et al. with the enzymes of Bao et al. and Kornfeld et al. in order to be sure that all mannose residues are phosphorylated. One would have been motivated to do so in view of the explicit suggestion by Kornfeld to use these enzymes for the modification of lysosomal enzymes for enzyme replacement therapy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty
Primary Examiner
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